Coughlin & Associates

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January 12, 2009

Ms. Fran Kammerer
Staff Counsel
Office of Environmental Health Hazard Assessment
1001 I Street
Sacramento, CA 95812

Subject: Proposition 65 Regulatory Update Project; Regulatory Concepts for Exposures to Human and Plant Nutrients in Human Food; Opportunity for Public Participation, Notice of Second Public Workshop [11/03/08] and Request for Public Comments due 1/12/2009

Dear Ms. Kammerer:

I am submitting these comments on behalf of several of my clients, in response to the subject notices published by the Office of Environmental Health Hazard Assessment ("OEHHA" or the "Agency"). I appreciated the opportunity to participate in and make oral comments at the public workshops held on this subject in Sacramento on April 18, 2008 and on December 12, 2008, and herein I am summarizing my oral comments delivered at the December 12 workshop and also providing additional explanatory comments.

I. Questions on Clarifications of "Possible Regulatory Language."

In my introductory oral comments, I pointed out that manganese (Mn) was recognized as both an essential plant nutrient and a human nutrient, and I asked OEHHA to clarify under which potential regulation (§ 25506 or § 25507) they would be considering setting a Maximum Daily Exposure for Mn. OEHHA responded that when a nutrient is both a plant and human nutrient, the exposure level would be set under the human nutrient section, and I agree with that determination.

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In addition, I asked OEHHA if they were aware of the important distinction between the two categories of recommended nutrient intakes set as Dietary Reference Intakes (DRIs) by the Institute of Medicine's Food and Nutrition Board (FNB). Based on the possible regulatory language concept discussed in the first Regulatory Concept and first workshop, I voiced my concern that OEHHA might believe that the only essential human nutrients recognized by the FNB were those designated with "Recommended Dietary Allowances" ("RDAs"), when in fact, those nutrients that are designated with "Adequate Intakes" ("AIs") are just as essential as the RDA nutrients, including vitamins D and K, calcium, chromium, manganese and potassium.

The only distinction between the two sets of recommended intakes is that the RDAs are known more precisely, whereas the AIs are only best estimates of recommended intakes due to more uncertainty in the requirements data. For those not very familiar with the tables provided by the FNB, the RDAs are set out in bold print, while the AIs are set out in unbolded print, a distinction that may be difficult to discern from a quick glance at the tables and the FNB's numerous published DRI volumes.

I also questioned and received OEHHA's clarification that only one "Maximum Daily Exposure from a Food (micrograms per day)" would be set for each human or plant nutrient. I raised this question because depending upon each specific plant's intrinsic requirement for an individual plant nutrient, the level of the nutrient in the finished food product will vary widely, and such level may trigger the need for a warning even if the product is considered one of the healthiest dietary choices available. I will address this issue in more detail below as well.

II. Issues Specific to the Plant Nutrients Manganese (Mn) and Boron (B).

I next presented a few Power Point slides (attached) as part of my oral presentation, specifically addressing the plant nutrients manganese (Mn) and boron (B) that OEHHA cited in footnote 1 as "…additional chemicals that may be considered for listing under Proposition 65…"

Slide 1 is identified as "Table 2: Relative Requirements of B for Some Agronomic and Horticultural Crops" (taken from the Internet). The table shows the Relative Requirement (high, intermediate, low) for B in various crops, many of which are high-value fruit, vegetable and nut

crops grown in California. The key point from this table is that all crops have an essential and varying B requirement for optimal growth and development, and these requirements dictate to a larger degree how much B must be added as fertilizer when soils are deficient in B. The varying requirements also help predict the B levels that will be found in the finished food products made from these crops, which is dependent on whether the crop is used alone to produce the finished product (e.g. wine, orange juice, apple juice) or whether the finished product is a mixture of several crops (e.g., V-8 juice, can of mixed nuts, medley of frozen vegetables).

When I showed this slide, I discussed the hypothetical example of two grape vineyards (with grapes being among those crops with a high relative requirement for B), one located in Sonoma County with significantly higher rainfall versus a vineyard located in the Temecula Valley (north of San Diego, semi-arid, with much less rainfall). With higher rainfall, the Sonoma vineyard would experience more natural depletion of B from the soil than would occur in Temecula, so the Sonoma growers will need to add more B fertilizer than the Temecula growers. While the B levels in the wines produced from both regions may be very similar, the task of determining the B levels in each wine that are naturally occurring vs. supplemented via fertilizer usage would be next to impossible. The Sonoma wines would surely have more B from fertilizer usage than the Temecula wines because of the higher B depletion that occurs in the rainier vineyards. And since there is no analytical method for B that can distinguish naturally occurring from supplemented B, fulfilling the burden of proof demanded in § 25507 for Plant Nutrients would be impossible for the wine manufacturers to achieve. Granted that wine already requires an alcohol warning message under Proposition 65, but this may not be broad enough to cover essential nutrients nor cover other grape-based products, such as juices produced from these different growing regions.

Slide 2 is identified as "Table 3: Relative response of selected crops to micronutrient fertilizers" (Michigan State University Extension website: attached as web1.msue.msu.edu/imp/modf1/visuals/e486v6.jpg). This table shows the relative response (high, medium, low) of six essential crop micronutrients (Mn, B, Cu, Zn, Mo, Fe) for a wide range of vegetable and field crops. The data in this table are similar to that in Slide 1, again demonstrating that different crops require and respond to different levels of added micronutrient fertilizers. The table's footnote points out that highly responsive crops will respond to fertilizer

additions if the micronutrient concentration in the soil is low, while low responsive crops do not usually respond to fertilizer additions even at the lowest soil micronutrient levels. These requirements and responses are largely intrinsic to the crop, although climate, weather conditions, soil type/acidity and other factors also determine individual micronutrient uptake. Thus, one could easily imagine that different varieties of oranges would have different levels of essential nutrients, as could oranges from Florida compared to oranges grown in California. Again, the burden of proof required by the regulation being considered here would be impossible for growers and food manufacturers to achieve.

In 2002 I co-published a paper with colleagues (Rainey et al., 2002; attached) on our determination of the daily B intake in the U.S. diet. We first developed a Boron Nutrient Database of the B content in over 3,600 individual foods and beverages, and these values represented 96% by weight of all the foods consumed by Americans of all ages. We then used the USDA's *Continuing Survey of Food Intakes by Individuals* (*CSFII*, 1994-1996), the latest comprehensive U.S. dietary intake data available at the time, to assess the daily B intake of the U.S. population. **Slide 3** is Table 2 from our paper, showing the Top 50 food/beverage contributors of B in the U.S. diet. For each product/food category, the table includes the percent contribution that each makes to the total daily B intake, the cumulative percent daily intake as each successive, ranked product/food category is added, and the B content or concentration (μg/100 g) of each product/food category.

The main point I expressed when discussing this table was that if an essential plant nutrient such as B were listed and OEHHA establishes a "Maximum Daily Exposure from a Food" (based on an as yet undetermined risk assessment methodology), there may be a line drawn across this table above which the food products will require a Proposition 65 warning and below which they will not require a warning. Even a cursory examination of the Top 50 listed products shows that many foods/beverages considered to be among the healthiest products eaten by California consumers are arrayed from the top to the bottom of the list, with plant-derived products being those with the highest levels of the nutrient and the highest contributors to daily intake. It is important to note that plant products (grains, fruits and vegetables) and beverages made from these products are the major food groups contributing the highest percentages of most

essential trace nutrients, and these food groups are known to be components of the very healthiest diets recommended by public health authorities globally.

III. Conclusions.

Based on the considerations presented here, I believe there is no scientific or public health justification for OEHHA to even consider going any further with this Regulatory Concept on Exposures to Human and Plant Nutrients. In addition, the possible Proposition 65 listing of essential nutrients is scientifically unjustified and would serve no public health need. For the reasons cited above, this Regulatory Concept lacks scientific merit and is actually counter productive to the optimization of the health of California consumers. Therefore, I urge OEHHA to drop consideration of this proposed regulatory scheme because it is not grounded in sound scientific principles, and because any warnings that might be triggered by the implementation of such a regulation would unnecessarily scare consumers away from smart and healthful food and nutrient choices.

Thank you for the opportunity to provide these comments. If you have any followup questions, please don't hesitate to contact me.

Sincerely,

James R. Coughlin, Ph.D.

cc (via email): Dr. Joan Denton
Ms. Carol Monahan-Cummings

Reference.

Rainey CJ, Nyquist LA, Coughlin JR and Downing RG. 2002. Dietary Boron Intake in the United States: CSFII 1994–1996. J. Food Composition and Analysis 15: 237–250.